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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,274	08/04/2006	Heinz Von Der Kammer	37998-237338	5018

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EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	PAPER NUMBER
1649	
MAIL DATE	DELIVERY MODE
05/22/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,274	VON DER KAMMER ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7 and 8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Claims 1-6 and 9-19 have been cancelled and claims 7 and 8 amended as requested in the amendment filed on April 13, 2009. Following the amendment claims 7 and 8 are pending in the instant application.

Claims 7 and 8 are under examination in the instant office action.

2. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3. Applicant's arguments filed on April 13, 2009 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Specification

4. The text of the instant specification remains not in compliance with the requirements for Sequence Identifiers, see reasons of record in section 3 of Paper mailed on January 12, 2009. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 8 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 stands indefinite for reciting limitation "recombinant animal which expresses KCNE4", see reasons of record in section 9 of Paper mailed on January 12, 2009. The metes and bounds of the limitation cannot be determined from the claim or he instant specification as filed.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 7 and 8 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial credible asserted utility or a well-established utility for reasons of record in section 12 of Paper mailed on January 12, 2009.

At pp. 11-12 of the Response, Applicant traverses the rejection by stating that the specification provided "the sequence for the KCNE4 protein and experimental data showing that patients diagnosed with Alzheimer's disease show a differential expression of the KCNE4 protein in their brain tissue when compared to a healthy brain tissue control. […] Moreover, Applicant has provided the working example found in Example 1 explaining the methods used to produce this data. Further description of the claimed screening methods as well as a definition of what constitutes a "modulator" are provided in paragraphs [0007], [0043], [0044], [0045], and [0046]. Taken together, one of skill in the art will appreciate that compounds found to be modulators of KCNE4 as shown in SEQ ID NO: 1 have a specific and credible utility for treating Alzheimer's patients in view of at least the evidence in the specification". Applicant's arguments have been fully considered but are not persuasive for the following reasons.

As fully explained in the previous office action of record, the disclosure of differential expression of KCNE4 protein in certain areas of the brain of patients with Alzheimer's disease (AD) does not directly correlate with assertion of a specific role of the KCNE4 in AD and therefore, does not support an assay that measures difference in activity or level of expression of KCNE4 for identification of potential pharmaceutical compounds. Moreover, since the activity of KCNE4 protein at the time of invention was not known or disclosed, it is not obvious as what parameter is supposed to be measured to practice the instant claimed method.

The only Example provided by the instant specification (Example 1) at p. 33 is limited to the description of measuring KCNE4 expression levels and provides no further support for the claimed method of screening for compounds that "decrease Alzheimer's disease". Moreover, since the claims do not require that any specific alteration in the level or activity of KCNE4, such as decrease or increase, identifies a compound that decreases AD, then by broadest reasonable interpretation, any compound would qualify as satisfying the limitations of the claims, which makes the instant methods meaningless.

In the decision of the U.S. Court of Appeals for the Federal Circuit *In re Fisher,* 2005 WL 2139421 (Sept. 7, 2005), the court interpreted *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (1966), as rejecting a "de minimis view of utility" 2005 WL 2139421, at *4. The *Fisher* court held that § 101 requires a utility that is both substantial and specific. *Id.* At *5. The court held that disclosing a substantial utility means "show[ing] that an invention is useful to the public as disclosed in its current form, not that it may be useful at some future date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show

that the claimed invention has a significant and presently available benefit to the public." *Id.* The court further held that a specific utility is "a use which is not so vague as to be meaningless." *Id.*

In the instant case, the specification discloses data related to tissue distribution of KCNE4 in brain tissue of patients with AD but discloses no utilities based on that data. Instead, what is claimed is a method of screening for a compound useful in treatment ("decrease") of AD, which represents at most a hypothetical possibility that KCNE4 is associated or involved with AD pathology, which is not substantial or specific "real world utility" by *Brenner* standard. Without knowledge of KCNE4 activity or its relevance to a specific physiological function altered during the course of AD, screening for compounds that affect ("alter") this unknown activity provides the barest information in regard to selection of a potential therapeutic drug. Thus, the assertion of "a specific and credible utility for treating Alzheimer's patients" by practicing the claimed method constitutes a utility that requires further research to identify or reasonably confirm a "real world" context of use, which, as it has been determined by the courts, does not support patentability.

For reasons of record in the previous communication of record and reasons above, the instant rejection is maintained.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 7 and 8 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

11. No claim is allowed.

12. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Olga N. Chernyshev, Ph.D.

May 20, 2009

/Olga N. Chernyshev/
Primary Examiner, Art Unit 1649